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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/985,974	11/07/2001	Jorge D. Brioni	6753.US.02	4598

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EXAMINER

BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/985,974

Applicant(s)

BRIONI ET AL.

Examiner

Mojdeh Bahar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) 1, 5, 15-22 and 26 (all in part), 3, 7, 10, 13, 24, 28 and 30 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 22 and 26 (all in part), 2, 4, 6, 8, 9, 11, 12, 14, 23, 25, 27, and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

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DETAILED ACTION

Applicant's response to the first office action, submitted April 28, 2003 (Paper No. 16) is acknowledged.

This application contains claims 1, 5, 15-22 and 26 (all in part), 3, 7, 10, 13, 24, 28 and 30 are drawn to nonelected species without traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 5, 15-22 and 26 (all in part in so far as they read on a male subject) and claims 2, 4, 6, 8-9, 11-12, 14, 23, 25, 27 and 29 are herein examined on the merits.

Claim Objections

Claim 1 is objected to because of the following informalities: The claim is not numbered. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 22 and 26 (all in part), 2, 4, 6, 8, 9, 11, 12, 14, 23, 25, 27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glase et al. and Zorn et al. in view of Sanner (USPN 5,714,487).

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Glase et al. Teaches that CP-226,629 is a D4 receptor agonist. Zorn et al. Teaches that N-[[4-(2-cyanophenyl)-1-piperazinyl]methyl]-3-methyl Benzamide is a known selective D4 receptor agonist, see particularly Table 1, compound 6.

Glase et al. and Zorn et al. Taken together do not teach that D4 receptor agonists are useful in treating male erectile dysfunction.

Sanner (USPN 5,714,487) teaches that Dopamine D-4 receptors may be beneficial in controlling vascular blood flow, see col.2, lines 1-3.

It would have been obvious to one of ordinary skill in the art to employ a D4 receptor agonist in a method of treating erectile dysfunction.

One of ordinary skill in the art would have been motivate to employ the claimed compounds in a method of treating erectile dysfunction because both are known D4 receptor agonists. Furthermore given the vasodilatory effect on Dopamine in general and D4 receptors in particular and that vasodilators are known to be useful in treating ED, the skilled artisan would reasonably expect similar therapeutic effects from D4 receptor agonists in treating ED.

Response to Arguments

In response to the obviousness rejection in the previous office action, applicant has merely states that "the cited references do not teach or suggest the use of D4 agonist for treating sexual dysfunction." Applicant has not presented any reasons why he believes that the cited references do not suggest or teach the instant invention.

In response to applicant's listing of the teachings of each of the prior art references, one cannot show nonobviousness by attacking references individually where the rejections are based

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on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar


RUSSELL TRAVERS
PRIMARY EXAMINER